

REMARKS

In the Office Action of November 29, 2007 claims 1 to 12 and 15 to 23 are pending of which claims 1 to 12 and 15 to 23 are rejected.

In particular:

- Claims 1, 3, 4, 9, 10 and 12 were rejected under 35 USC 102(b) as being anticipated by Brown et al (US 5,769,887).
- Claims 2, 5, 6, 8, 17 to 20, 22 and 23 are rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096).
- Claims 7, 11, 15 and 16 are rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of Greenberg et al (US 2002/0198587).
- Claim 21 is rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of in view of Aiba et al (US 6,221,096) and further in view of Greenberg et al (US 2002/0198587)

CLAIM AMENDMENTS

Claims 1 and 10 are amended to specify that the links joining adjacent stents are flexible links. This terminology was used in original claim 4.

Claims 3 and 4 are cancelled as being superfluous.

Claims 15 and 16 are cancelled.

DISCUSSION

Independent apparatus claims 1, 10, 17 of this present application, as amended, each claim a prosthesis which is specifically designed for the treatment, by intraluminal placement, of aortic dissection caused by a rupture in the wall of an aorta of a patient. The prosthesis has a number of self expanding stents flexibly linked together by links with at least one of the stents having a biocompatible graft material cover defining a covered portion and the balance defining an uncovered portion. Support for the terms "covered portion" and "uncovered portion" can be found on page 10 lines 10 to 12 of the specification, for instance.

The importance of the covered portion is that it can be positioned to close off the rupture in the wall of a lumen which occurs with an aortic dissection.

Serial No. 10/762,963

PATENT

The uncovered portion is equally important as once deployed it provides continuous steady pressure on the wall of the lumen adjacent to, and extending away from, the rupture to deflate the false lumen caused by a aortic dissection. It may take some time, days or weeks, for the false lumen to deflate and during this time the steady pressure of a self expanding stent assists with this deflation. The importance of the use of self expanding stents for the provision of this pressure to deflate the false lumen resulting from an aortic dissection is discussed on page 9 of the specification in the paragraph which discusses Figure 5.

We refer the examiner to the portion of page 9 which states:

"The stents provide gradual pressure on the wall of the lumen to close the false lumen and open up the true lumen."

It should be particularly noted by the Examiner that the claim defines self-expanding stents as these are elastic and will tend to provide continuous pressure against the wall of a lumen after deployment.

The claims also specifies that the self expanding stents are linked together by flexible links. The flexible links are important to allow various parts of the uncovered portion to expand at different rates as the false lumen deflates and to also to allow for bends or curves in the descending aorta, that region of the aorta in which an aortic dissection often occurs.

Balloon expandable stents cannot be used for such a process because they are instantly expanded to their full size and such a rapid expansion could rupture the wall of the aorta in the region of the false lumen with fatal results. They do not provide continuous pressure.

The use of uncovered stents to provide pressure on the wall of the lumen adjacent to an extending away from the rupture to deflate the false lumen is also important because in this region there may be branch vessels such as the mesenteric arteries extending from the aorta and an uncovered stent will not cause occlusion of these branch vessels. Occlusion could result in partial paralysis in a patient.

It is also important that the prosthesis of the present invention is a single component so that it can be quickly deployed when necessary. A significant number of aortic dissections are caused by accidental trauma and speed is of the essence in treatment. Having only a single component to deliver to the rupture site in the aorta means that treatment can be achieved quickly.

Serial No. 10/762,963

PATENT

Hence there are several important feature for a prosthesis of the present invention . For treatment of aortic dissection the prosthesis of the present has:

- A covered portion with a stent inside to close off the initial rupture
- An uncovered portion to provide pressure on the wall of the false lumen
- Flexible links to allow for variable deflation and curves.
- The stent are self expanding stents

We submit that none of the cited references whether taken singly or in any combination teach or suggest this set of features.

Brown et al (US 5,769,887)

The reference Brown et al teaches an unstented tubular graft with a single exposed stent fastened to one end. The exposed stent can be balloon expanded or self expanding but there is no teaching or suggestion that there are a number of stents linked together by flexible stents. The examiner has referred us to item 23 , tie bars (column 4 line 24), but there are not flexible links. Hence Brown does not teach the four essential features as enumerated above and we submit that claims 1, 10 and 17 are not anticipated by Brown et al (US 5,769,887).

Aiba et al (US 6,221,096).

This reference teaches a self expanding stent which may be covered or uncovered but which is placed temporarily into the body but never actually released from wires which extend to outside the body. The wires (15) are welded or brazed to the elastic rings (14) (column 4 lines 3 to 7) so the portion 13 cannot be considered of as a series of stents linked together by flexible links. We further note that Aiba either teaches an entirely covered stent or an uncovered stent it does not teach a combination of these. We submit that the features of claims 2, 5, 6, 8, 17 to 20, 22 and 23 which are not taught or suggested by Brown are also not taught or suggested in Aiba and hence we submit that claims 2, 5, 6, 8, 17 to 20, 22 and 23 are patentable under 35 USC 103(a) over Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096).

Greenberg et al (US 2002/0198587).

The reference Greenberg teaches a series of stents stitched to a graft material tube and a single uncovered stent. There is no teaching of uncovered stents linked

Serial No. 10/762,963

PATENT

together by flexible links. We submit that the features of claims 7, 11 and 21 which are not taught or suggested by Brown or Aiba are also not taught or suggested in Greenberg and hence we submit that claims 7, 11 and 21 are patentable under 35 USC 103(a) over Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096) and further in view of Greenberg (US 2002/0198587).

We further submit that the dependant claims 2, 5, 6, 7, 8, 9, 11, 12, 17 to 23 depend from a patentable claims 1, 10 and 17 and are themselves patentable and not anticipated.

The rejections to claims 3, 4, 15 and 16 is rendered moot by the cancellation of these claims.


The re-examination and reconsideration of this application is respectfully requested and it is further requested that this application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,
David Ernest Hartley
Ian Nixon
Peter John Mossop

Date: Feb 11, 2008

By


Richard J. Godlewski
Reg. No. 30,056
(812) 330-1824